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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,977

05/02/2007

Haijun Sun

X-18530

2166

25885 7590 02/18/2010

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PATENT DIVISION

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EXAMINER

DEBERRY, REGINA M

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

02/18/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,977	SUN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-67 is/are pending in the application.
- 4a) Of the above claim(s) 62-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/21/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of Application, Amendments and/or Claims

The amendment, filed 02 November 2009, has been entered in full. Claims 1-59 are canceled. New claims 60-67 are added.

Applicant's election with traverse of Group I (previous claims 1-27 and 33, drawn to the antibody and the pharmaceutical composition comprising the antibody) and the heavy chain variable region comprising SEQ ID NO:15 and light chain variable region comprising SEQ ID NO:16, in the reply filed on 02 November 2009 is acknowledged.

The traversal is on the ground(s) that Ruben et al., do not destroy unity of invention of the pending claims and that the newly presented claims possess unity of invention as the claims possess a unifying technical feature. Applicant discusses the Restriction/Election and the art of record (Ruben et al., US Patent 6,077,692) used to break unity in the previous Office Action. Applicant discusses Ruben et al., specifically column 22, line 21-column 25, line 7. Applicant argues that the Examiner is alleging that an antibody to the ligand KGF-2 or to a polypeptide exhibiting KGF-2 activity will also bind to the receptor FGFR1-IIIb. Applicant argues that the Examiner has not provided a reasonable basis to conclude that antibodies made against KGF-2 will bind FGFR1-IIIb. Applicant argues that the cited portion of Ruben et al. do not relate to an antibody or antigen-binding fragment thereof that will bind to FGFR1-IIIb. Applicant argues that newly presented claims 60-67 are not disclosed in Ruben et al. and is the special technical feature which provides the unity of invention amongst the claims.

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Applicant's arguments have been fully considered but are not deemed persuasive. **Applicant cannot compare newly presented claims 60-67 to Ruben et al., when the Restriction/Election, lack of unity and art of record was made on canceled claims 1-59.** Canceled claim 1 was drawn to a purified antibody or fragment thereof which specifically binds to a fibroblast growth factor receptor FGFR-1(IIIb) or FGFR-1(IIIc) or FGFR-4(IIIc). As was stated in the previous Office Action, Ruben et al. teach that KGF-2 binds the FGFR-1(IIIb). Ruben et al. teach antibodies made against KGF-2. Further, Ruben et al. teach antibodies fused to KGF-2. Ruben et al. teach that this offers therapeutic advantages in serum half-life (column 25, lines 28-43). Ruben et al. teach that KGF-2 is fused to the constant domain of the IgG antibody. The resulting molecule would comprise a fragment of an antibody (i.e. constant domain of immunoglobulin IgG) which binds FGFR-1(IIIb) because it is fused to KGF-2. This molecule has KGF-2 activity.

Applicant argues that claims 60-67 read on the elected species. This is not found persuasive. New claims 62-67 would be restricted to different Groups. The special technical feature of claims 62-64 would be the nucleic acid encoding the antibody, expression vector and host cell. The special technical feature of claim 65 would be a method of treating obesity. The special technical feature of claim 66 would be a method of treating diabetes. The special technical feature of claim 67 would be a method of reducing food intake or a condition affected by reducing food intake comprising.

The requirement is still deemed proper and is therefore made **FINAL**. Claims 62-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02 November 2009. Claims 60 and 61 are under examination.

Information Disclosure Statement

The information disclosure statement(s) (IDS) (filed 21 January 2009) was received and complies with the provisions of 37 CFR §§1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits. This applies only to the U.S. Patents and most of the foreign documents. The other references fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 for the following reasons.

Reference WO 2005/037235 states on the first page, "takes the place of EP1680140 A2; art. 153 of the EPC". Reference WO 2005/037235 fails to comply because the Examiner cannot consider a reference which is not made of record (i.e. listed on a 1449).

The scientific journal references fail to comply because they are missing the titles of the articles.

References Burdon and Sambrook et al. fail to comply because the submitted pages are only to the contents of the references. Books may be identified by the publisher, title, author, relevant pages of the publication, date and place of publication.

The instant references will be lined through and not considered by the Examiner. The reference have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is invited to resubmit a particular reference(s) that they want to be considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a). Also see MPEP 609.04(a), 609.04(b), 609.05 [R-3] and 37 CFR 1.97 and 37 CFR 1.98.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 60 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claim reads on products of nature. Amending claim 60 to recite, “an ***isolated*** FGFR1(IIIc) antibody...”, would be remedial.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 60 does not clearly state what the antibody binds. Amending the claim to recite, "an **isolated** FGFR1(IIIc) antibody or binding fragment thereof **that binds antigen FGFR1(IIIc)**, said antibody or binding fragment thereof comprising a heavy chain variable region (HCVR) and a light chain variable region (LCVR), wherein the HCVR comprises the amino acid sequence of SEQ ID NO:15 and the LCVR comprises the amino acid sequence of SEQ ID NO:16", would be remedial.

Claim 61 recites the limitation "**antigen-binding** fragment thereof" but depends from claim 60 which recites, "binding fragment thereof". There is insufficient antecedent basis for this limitation in the claim. Further, the difference between "binding fragment thereof" (claim 60) and "**antigen-binding** fragment thereof" (claim 61) is unclear. The Examiner could not find the definitions in the instant specification. Clarification is requested.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the

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organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

/R. M. D./
Examiner, Art Unit 1647
2/3/10